



MATERIAL SAFETY DATA SHEET

1 PRODUCT AND COMPANY IDENTIFICATION

Product Name: Acepromazine Maleate Injection

Product No.: NADA 117-531

GHS Product Identifier: Not applicable

Synonyms: Not available

Molecular Formula: Mixture, not applicable

Molecular Weight: Not applicable

CAS Number: Mixture, not applicable

Chemical Family: Phenothiazine Tranquilizer/Sedative

Manufacturer:

Boehringer Ingelheim Vetmedica, Inc.
2621 North Belt Hwy
St. Joseph, MO 64506-2002

Emergency Telephone:

Transportation Emergency: (800) 424-9300

Medical Emergency (24HR): (800)530-5432

Intended Use:

Tranquilization aid and preanesthetic agent in
dogs, cats and horses

Non-emergency Telephone: (800) 821-7467

2 HAZARDS IDENTIFICATION

Emergency Overview

Physical State: 50mL multidose vial of 10mg/mL sterile liquid

Color: Yellow

Odor: Odorless



WARNING!

Harmful if swallowed-For dog, cat and horse injection only.

Not for human use.

May cause drowsiness or dizziness.

Causes eye irritation.

Precautionary Statements:

Accidental human injection can cause serious local reactions or anaphylactic reaction and systemic effects.

Not for use in animals intended for food.

Keep only in original container.

Keep at a temperature not exceeding 30° C.

Fire-fighting: Use foam, carbon dioxide, dry powder and water fog or material appropriate for surrounding fire.

Avoid contact with eyes, skin and clothing.

Wash thoroughly with soap and water after handling.

Wear suitable gloves and eye/face protection.

Spills: Cover with absorbent or contain. Collect and dispose.

In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

If swallowed, seek medical advice immediately and show this container or label.

In case of contact with eyes, rinse immediately with plenty of water for at least 15 minutes. Get medical attention.

This material and its container must be disposed of in a safe way.

Keep out of reach of children.

Keep away from food, drink, and animal feedstuffs.

Acute effect:

Hypotension can occur after rapid intravenous injection causing cardiovascular collapse.

Tranquilizers are potent central nervous system depressants and they can cause marked sedation with suppression of the sympathetic nervous system.

May produce an additive action when given in conjunction with other depressants.

Will potentiate general anesthesia.

In horses, paralysis of the retractor penis muscle has been associated with the use of phenothiazine derivative tranquilizers. The risk should be duly considered prior to administration to male horses (castrated and uncastrated).

Accidental Intracarotid injection in horses can produce clinical signs ranging from disorientation to seizures to death.

Precautions/Contraindications:

Should be avoided in pregnant or lactating animals. Should be used with caution in older animals, animals with liver disease, heart disease, injury or debilitation. Should not be used in animals with a history of epilepsy, those prone to seizures or those receiving a myelogram (lowers the seizure threshold). Should not be used in animals with tetanus or strychnine poisoning. Use with caution in giant dog breeds and greyhounds due to their increased sensitivity to acepromazine.

Overdosage:

Overdose can cause excessive sedation, slow respiratory and heart rate, pale gums, unsteady gait, poor coordination, and inability to stand. May cause sudden collapse, unconsciousness, seizures and death. Phenylephrine and norepinephrine are the drugs of choice to treat acepromazine-induced hypotension. Barbiturates or diazepam may be used for the treatment of seizures associated with overdose.

ADVERSE REACTIONS TO PRODUCT: May cause marked sedation with suppression of the sympathetic nervous system. Can produce prolonged depression or motor restlessness when given in excessive amounts or when given to sensitive animals. Idiosyncratic reactions may occur in dogs following oral or parenteral administration. Symptoms include potentially serious adverse reactions including behavioral disorders such as aggression, biting, chewing, and nervousness. Penile paralysis is a recognized side effect of acepromazine in the horse. Should be avoided in breeding stallions.

Potential Health Effects

Inhalation: Not expected to be an inhalation hazard.

Eye Contact: Not expected to be a hazard to the eye with prescribed use. Exposure to liquid in eye may cause eye irritation.

Skin Contact: Can cause hypersensitive reactions.

Ingestion: Not expected to be an ingestion hazard with prescribed use. Harmful. Ingestion may cause vomiting, nausea, dizziness, drowsiness or other systemic effects.

Injection: May cause drowsiness or dizziness.

Chronic Health Effects: Possible hypersensitization (development of abnormal sensitivity).

Target Organ(s): Central Nervous System

Potential Physical Effects: Decreases anxiety causes central nervous system depression, a drop in blood pressure and heart rate.

OSHA Regulatory Status: Nonhazardous, exempt

Environment: No data available

3	COMPOSITION / INFORMATION ON INGREDIENTS
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Chemical Name	EC No.	CAS- No.	Concentration	Classification	Notes
Acepromazine maleate	2227489	3598-37-6	10mg/mL	Xn; R22; R36	----
Benzyl alcohol	2028599	100-51-6	1%	Xn; R20/22	Norway
Sodium citrate, dihydrate	2006753	6132-04-3	proprietary	----	----
Citric acid, monohydrate	2010691	5949-29-1	proprietary	----	----
Water	2317912	7732-18-5	proprietary	----	----

The full texts for all R-Phrases are displayed in Section 16.

4 FIRST AID MEASURES

General: Animals or persons developing anaphylactic (life-threatening) reactions, such as difficulty in breathing or unconsciousness, must receive immediate medical attention.

Inhalation: Move to fresh air. Treat symptomatically. Get medical attention if symptoms persist.

Eye Contact: Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention.

Skin Contact: Wash with soap and water. Get medical attention if symptoms occur.

Ingestion: Call a physician or poison control center immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconscious person.

Injection: In case of accidental injection, wash the site thoroughly. Seek medical attention immediately.

Note to Physician: For animal injection only. Not for human use. Epinephrine is contraindicated for treatment of acute hypotension caused by phenothiazine derivative tranquilizers since further depression of blood pressure can occur. Other pressor amines, such as norepinephrine or phenylephrine are the drugs of choice. Barbiturates or diazepam may be used for the treatment of seizures associated with overdose.

5 FIRE-FIGHTING MEASURES

Extinguishing Media: Extinguish with foam, carbon dioxide, dry powder and water fog or material appropriate for surrounding fire.

Unsuitable Extinguishing Media: None known

Special Fire Fighting Procedures: Wear self-contained breathing apparatus and protective clothing.

Unusual Fire & Explosion Hazards: None known

Hazardous Combustion Products: Carbon monoxide, carbon dioxide.

Flammability Class: 0

6 ACCIDENTAL RELEASE MEASURES

Personal Precautions: Wear appropriate personal protective equipment. (See Section 8).

Spill Cleanup Methods: STEPS TO BE TAKEN IF SIGNIFICANT QUANTITIES OF LIQUID IS SPILLED: Eliminate all ignition sources. Wear an approved respirator, eye protection, personal protective coverings and gloves. Use HEPA filtered vacuum or wet sweeping to clean up spillage. Place spillage in appropriate container for waste disposal. Wash contaminated clothing before use.

Environmental Precautions: Prevent runoff from entering drains, sewers or streams. Dike for later disposal.

7	HANDLING AND STORAGE
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Handling: Avoid contact with eyes. Avoid accidental injection. Do not taste or swallow. Wash thoroughly with soap and water after handling.

Storage: Keep only in the original container. Store at 15°-30° C (59°-86° F). Store away from foodstuffs.

8	EXPOSURE CONTROLS / PERSONAL PROTECTION
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Exposure Limits:

Chemical Name	Source	Type	Exposure Limits	Notes
Acepromazine maleate	-----	----	N/A	----
Benzyl alcohol	AIHA	8-HR TWA	10 ppm	----
Benzyl alcohol	Bulgaria Regulation No. 13	OELs	5.0 mg/m ³	----
Citric acid, monohydrate	----	----	N/A	----
Sodium citrate, dihydrate	----	----	N/A	----
Water	----	----	N/A	----

Engineering Controls: Not generally required when handling containers or liquid. (See exposure limits). Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions.

Respiratory Protection: Not generally required when handling containers or liquid. If engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (in countries where exposure limits have not been established), an approved respirator must be worn. In the United States of America, if respirators are used, a program should be instituted to assure compliance with OSHA standard 63 FR 1152, January 8, 1998. Respirator type: NIOSH approved air-purifying respirator with an appropriate, government approved (where applicable), air-purifying filter, cartridge, or canister.

PERSONAL PROTECTIVE EQUIPMENT: Not generally required when handling containers. If containers are compromised or exposure to the active ingredient or mixture is likely wear:

Eye Protection: Wear safety glasses with side shields (or goggles).

Hand Protection: Wear suitable gloves.

Skin Protection: It is a good industrial hygiene practice to minimize skin contact.

Hygiene Measures: Eye bath, washing facilities

9 PHYSICAL AND CHEMICAL PROPERTIES

Color: Yellow
Odor: Odorless
Odor Threshold: No data available
Physical State: 50mg – Multidose vial of 10mg/ml liquid
pH: ~ 5.3
Melting Point: No data available
Freezing Point: No data available
Boiling Point: 110° C (212°F)
Flash Point: > 93°C (200°F)
Flammability Limit – Upper (%): No data available
Flammability Limit – Lower (%): No data available
Evaporation rate: No data available
Vapor Pressure: No data available
Vapor Density (Air=1): No data available
Specific Gravity: No data available
Solubility: Miscible
Partition Coefficient (n-Octanol/water): No data available
Autoignition Temperature: Not applicable
Decomposition Temperature: No data available

10 STABILITY AND REACTIVITY

Stability: Stable

Conditions to Avoid: None known

Incompatible Materials: Strong oxidizing agents

Hazardous Decomposition Products: None known

Possibility of Hazardous Reactions: Hazardous polymerization will not occur.

11 TOXICOLOGICAL INFORMATION

Specified Substances

Acute Toxicity

Chemical Name	Test Results
Acepromazine maleate	Oral LD ₅₀ (rat): 400 mg/kg Intravenous LD ₅₀ (rat): 65 mg/kg Oral LD ₅₀ (mouse): 270 mg/kg Subcutaneous LD ₅₀ (mouse): 175 mg/kg
Benzyl alcohol	Oral LD ₅₀ (rat): 1230 mg/kg Oral LD ₅₀ (rat): 3100 mg/kg

	Oral LD ₅₀ (mouse): 1580 mg/kg
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Listed Carcinogens: None

12 ECOLOGICAL INFORMATION

Ectotoxicity: No data available

Persistence and degradability: No data available

Mobility in soil: No data available

Other adverse effects: No data available

Germany WGK: Benzyl alcohol: ID No: 216; Class: 1: slightly water-endangering; Benzyl alcohol: ID No: 216; Class 1: slightly water-endangering; Citric acid: ID 57; Class 1: slightly water-endangering; Sodium citrate dihydrate: ID No: 2203; Class 1: slightly water-endangering;

13 DISPOSAL CONSIDERATIONS

General Information: Dispose of in accordance with local, state and federal regulations.

Disposal Methods: No specific disposal method required. Do not empty into drains; dispose of this material and its container in a safe way. Do not contaminate water, food, or feed by storage disposal.

Container: Since emptied containers retain product residue, follow label warnings even after container is emptied.

14 TRANSPORT INFORMATION

DOT: Not regulated

TDG: Not regulated

ADR/RID: Not regulated

IATA: Not regulated

IMDG: Not regulated

15 REGULATORY INFORMATION

Canadian Controlled Products Regulations: This product has been classified according to the hazard criteria of the Canadian Controlled Products Regulations, Section 33, and the MSDS contains all required information.

WHMIS Classification: Noncontrolled, exempt

Inventory Status

This material is **not** listed on the US TSCA Inventory. Therefore, it can only be used for TSCA exempt purposes such as R&D or veterinary use.

This material is **not** listed on the DSL Inventory.

US Regulations

FEDERAL LAW RESTRICTS THIS DRUG TO LICENSED VETERINARIANS.

FDA Status: Benzyl alcohol GRAS

State Regulations

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): None

Massachusetts Right-To-Know List: Benzyl alcohol

Minnesota Hazardous Substances List: Benzyl alcohol

New Jersey Right-To-Know List: None

Pennsylvania Right-To-Know List: Benzyl alcohol

European Regulations

Switzerland Toxins List 1: alpha-Hydroxytoluol: Toxicity Category: 4; Sodium citrate dihydrate: Toxicity Category: None: possible sensitizer, carcinogenic potential.

16	OTHER INFORMATION
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Hazard Ratings

	Health Hazard	Fire Hazard	Reactivity Hazard
HMIS	2	0	0

	Health Hazard	Fire Hazard	Reactivity Hazard	Special Hazard
NFPA	2	0	0	N/A

*- Chronic health effect; 0 – Minimal; 1 – Slight; 2 – Moderate; 3 – Serious; 4 – Severe

Xn - Harmful

R20 -Harmful by inhalation.

R22 - Harmful if swallowed.

R36 - Irritating to eyes.

S25 - Avoid contact with eyes.

S26 - In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

S46 - In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

ABBREVIATIONS:

BIV - Boehringer Ingelheim Vetmedica, Inc.

AIHA- American Industrial Hygiene Association

mppcf – million particles/cubic foot

N/A - Not applicable.

N/E - Not established.

References:

1. Freedom of Information Summary. ANADA 200-361. Acepromazine Maleate Injection, Tranquilizer. Boehringer Ingelheim Vetmedica, Inc. April 2004.
www.fda.gov
2. Freedom of Information Summary. ANADA 200-319. Acepromazine Maleate Injection 10mg/ml Phoenix Scientific, Inc., St. Joseph, MO. March 25, 2003.
www.fda.gov
3. Acepromazine Maleate Injection and Tablets. Product Reference Information. Boehringer Ingelheim Vetmedica, Inc. www.bi-vetmedica.com
4. Acepromazine Maleate Injection. Product Label. Boehringer Ingelheim Vetmedica, Inc. www.bi-vetmedica.com
5. Ariel WebInsight Regulatory Database. Regulatory Summary for North America, Western Europe, and Global Inventories Database. Benzyl Alcohol, Acepromazine Maleate.
6. RTECS – Benzyl Alcohol. RTECS No. DN3150000
7. GHS Manual

Revision Information: Updated all sections of the MSDS for ANSI, GHS and OSHA Compliance.

Prepared by: Boehringer Ingelheim Vetmedica, Inc.

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